

Appl. No. 10/622,313  
Amdt. dated May 30, 2007  
Reply to Office Action of November 30, 2006

PATENT

**Amendments to the Drawings:**

Please DELETE Figure 1, the contents of which are provided in SEQ ID NO:1.

**REMARKS/ARGUMENTS**

**Status of the Claims**

Upon entry of the present amendment, claims 18-20, 25-27, 32, 37-41, 44-59, 61-62, 64-67, 69 and 71-77 are pending. Claims 19-20, 25-27, 41, 44-49, 51-54 and 65-67 are withdrawn from examination as directed to a non-elected invention. Claims 1-17, 21-24, 28-31, 33-36, 42-43, 54, 60, 63, 68 and 70 are canceled without disclaimer or prejudice to renewal. Applicants reserve their right to pursue canceled claims in a continuation or divisional patent application.

Claims 18-19, 27, 32, 37-40, 50, 52, 55-59, 64 and 72 are amended and new claims 73-77 are added.

Claims 18-19 are amended to be commensurate in scope with claim 32.

Claim 27 is amended to depend from claim 32.

Claim 32 is amended to set forth an isolated antibody that specifically binds an epitope of a P2X<sub>7</sub> receptor extending from Gly200 to Cys216 of SEQ ID NO:1. Support is found, for example, in paragraphs [0020], [0043], [0126] and in claims 11, 13 and 39 as originally filed. Support for setting forth skin cancer is found, for example, in paragraphs 0041 and 0110.

Claim 37 is amended to set forth proper Markush group language.

Claims 38-40 are amended to reference SEQ ID NO:1.

Claim 50 is amended to reference skin cancer. Support is found, for example, in paragraphs [0041] and [0110].

Claim 52 is amended to be commensurate in scope with claim 32.

Claim 55 is amended to set forth proper Markush group language.

Claim 56 is amended to clarify that a radiolabel is attached to the antibody.

Claim 57 is amended to change "when" to "wherein."

Claim 58 is amended to clarify that a fluorescent label is attached to the antibody.

Claim 59 is amended to clarify that a matrix is attached to the antibody.

Claim 64 is amended to set forth an antibody that binds to an epitope of a P2X<sub>7</sub> receptor extending from Gly200 to Cys216 of SEQ ID NO:1. Support is found, for example, in paragraphs [0020], [0043], [0126] and in claims 11, 13 and 39 as originally filed.

Claim 72 is amended to set forth that the proline at amino acid 210 is in the cis conformation. Support is found, for example, in paragraphs [0012], [0020], [0043] and [0098].

New claim 73 finds support, for example, in paragraph [0020].

New claims 74-77 find support, for example, in paragraphs [0104] and [0110].

**Request for Rejoinder under M.P.E.P. § 821.04**

Claims 18-20, 25-26, 52 and 54 are withdrawn from examination as being drawn to a non-elected invention. Claims 32, 37-40, 55-59 and 18-20, 25-26, 52, 54 are related as composition and methods of use. Upon entry of the present amendments, Applicants believe that composition claims 32, 37-40, 55-59 are allowable. Accordingly, pursuant to M.P.E.P. § 821.04, Applicants respectfully request withdrawal of the restriction requirement with respect to composition claims 32, 37-40, 55-59, and method claims 18-20, 25-26, 52, 54, and examination of the withdrawn methods of use claims. In accordance with M.P.E.P. § 821.04, Applicants have amended claims 18-20, 25-26, 52, 54 such that their scope corresponds to claim 32.

**Information Disclosure Statement**

The Examiner has requested that copies of references AB-AJ be submitted. In response, Applicants submit with this amendment a Supplemental IDS and copies of references AB-AJ.

The Examiner has requested submission of copies of domestic priority documents PCT/AU02/00061 (published as WO 02/057306) and PCT/AU02/01204 (published as WO 03/020762) and foreign priority documents PR2579, PR5890, PR5891, PR7490 and PR7431. In response, Applicant submit with this amendment copies of WO 02/057306 and WO 03/020762, and certified copies of PR2579, PR5890, PR5891, PR7490 and PR7431.

**Drawings**

The Examiner objected to Figure 1 for containing a protein sequence that is included in its entirety in the sequence listing. In response, Applicants have deleted Figure 1 and amended the specification to reflect this.

**Specification**

The Examiner objected to the title as not descriptive. Applicants do not necessarily agree with the Examiner's position. However, in the interest of furthering prosecution, Applicants have amended the title in accordance with the Examiner's suggestion.

The Examiner has requested that the use of trademarks in paragraphs [0095], [0096] and [0125] be capitalized. In response, Applicants have amended paragraphs [0095], [0096] and [0125].

The Examiner objected to the abstract for containing more than 150 word and multiple paragraphs. In response, Applicants have amended the abstract to be one paragraph of less than 150 words.

**Claim Objections**

The Examiner's objections to claims 6, 11, 12, 14 and 42 are rendered moot by cancellation of these claims.

The objection to claim 50 is addressed by deleting the language found objectionable by the Examiner.

The objection to claim 57 is obviated by amending the claim in accordance with the suggestion of the Examiner.

**Rejection under 35 U.S.C. § 101**

The Examiner has rejected claims 32, 37-40 and 55 under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter. Claims 7-8, 11-13, 33-36 and 42 are canceled. Applicants do not necessarily agree with the Examiner. However, in the interest of furthering

prosecution, Applicants have amended claim 32 to set forth an isolated antibody. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

**Rejection under 35 U.S.C. § 112, second paragraph**

Applicants reference rejected, pending claims below.

Claims 32, 38 and 72 are rejected under 35 U.S.C. § 112, second paragraph, for setting forth the phrase “adapted to distinguish/detect.” Applicants do not necessarily agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended claims to set forth “distinguishes.”

Claims 32, 38-40, 50 61-62 and 72 are rejected for reciting P2X<sub>7</sub> without reference to a SEQ ID NO. The Examiner alleges that the recitation of the name P2X<sub>7</sub> is insufficient to indicate the metes and bounds of the claims because allegedly the term P2X<sub>7</sub> was not well-established in the art at the time the invention was filed. Applicants respectfully disagree with the Examiner. Applicants provide a PubMed search showing that P2X<sub>7</sub> receptors were widely known in the art at the time of the January 17, 2001 priority date of the present application.<sup>1</sup> However, in the interest of furthering prosecution, Applicants have amended claims to set forth SEQ ID NO:1, as suggested by the Examiner.

Claims 37 and 55 are rejected for reciting “fragment thereof” at the end of a Markush listing. Applicants respectfully disagree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended claims 37 and 55 to set forth “an antigen binding fragment of each antibody type.” Applicants have also removed the term “appropriate” from claim 37.

The Examiner’s rejection of claim 8 is rendered moot by the cancellation of this claim.

Claims 38-40, 64 and 72 are rejected for reciting amino acid positions without reference to a sequence. Applicants do not necessarily agree with the Examiner. However, in

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<sup>1</sup> PubMed search results for “P2X<sub>7</sub>” from January 1, 1995 through January 10, 2001 retrieved 119 results published before January 17, 2001 priority date of the present application. Attached as Exhibit A.

the interest of furthering prosecution, claims 38-40, 64 and 72 have been amended to set forth SEQ ID NO:1.

The rejection of claims 11 and 12 is rendered moot by their cancellation.

Claim 50 is rejected for reciting "aberrant or non-functional P2X<sub>7</sub> receptors."

Applicants do not necessarily agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended claim 50 to delete the language found objectionable by the Examiner.

Claims 56, 58 and 59 are rejected for reciting the phrase "when combined with." In response, Applicants have amended claims 56, 58 and 59 to set forth that the recited moiety is attached to the antibody.

Claims 61-62 are rejected for reciting a "normal" expression profile. Applicants respectfully traverse. Read in the context of the specification, those of skill would readily recognize the metes and bounds of what Applicants intended by "normal profile," *e.g.*, from an individual not having skin cancer. That a normal expression profile correlates with the expression of functional P2X<sub>7</sub> receptors and absence of disease finds support, for example, in paragraphs 0017, 0022, 0029, 0046, 0104, 0109 and 0110.

The Examiner has rejected claim 57 for depending from an indefinite claim. In response, this rejection is obviated by the amendment of claim 55.

In view of the foregoing, the Examiner is respectfully requested to withdraw the rejections under 35 U.S.C. § 112, second paragraph.

**Rejection under 35 U.S.C. § 112, first paragraph, enablement requirement**

The Examiner has rejected claims 32, 37-40, 50, 55-59, 61-62 and 64 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner acknowledges that the specification is enabling for (1) an isolated antibody that specifically binds to residues G200-C216 of SEQ ID NO:1, as well as compositions comprising the same and a pharmaceutically acceptable carrier; and (2) an isolated antibody that specifically binds to residues G200-T215 of SEQ ID NO:1, as well as compositions comprising the same and

a pharmaceutically acceptable carrier. *See*, pages 11 and 14 of the present Office Action. The Examiner also concedes that the specification is enabling for pharmaceutical compositions and the treatment of skin cancer.

Applicants do not necessarily agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended the claims to set forth an antibody that specifically binds an epitope within residues Gly200 to Cys216 of SEQ ID NO:1 and its use in the treatment, prevention, diagnosis and/or detection of skin cancer. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

**Rejection under 35 U.S.C. § 112, first paragraph, written description requirement**

The Examiner has rejected claims 32, 37-40, 50, 55-59, 61-62 and 64 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner acknowledges that the specification describes (1) an isolated antibody that specifically binds to residues G200-C216 of SEQ ID NO:1; and (2) an isolated antibody that specifically binds to residues G200-T215 of SEQ ID NO:1. *See*, pages 18-20 of the present Office Action.

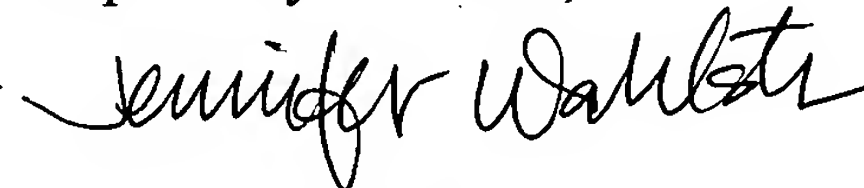
Applicants do not necessarily agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended the claims to set forth an antibody that specifically binds an epitope within residues Gly200 to Cys216 of SEQ ID NO:1. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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